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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

JHP PHARMACEUTICALS, LLC, a Delaware limited liability company,	)	Case No. CV 13-07460 DDP (JEMx)
	)	
Plaintiff,	)	<b>ORDER GRANTING IN PART AND</b>
	)	<b>DENYING IN PART DEFENDANTS'</b>
	)	<b>MOTIONS TO DISMISS</b>
v.	)	
	)	[Dkts 60 & 61]
HOSPIRA, INC., a Delaware corporation; INTERNATIONAL MEDICATION SYSTEMS, LTD., a Delaware corporation; and AMERICAN REGENT, INC., a New York corporation,	)	
	)	
Defendants.	)	
_____	)	

Presently before the court are two motions to dismiss the complaint brought by Par Sterile Products, LLC, against the Defendants American Regent, Inc., Hospira, Inc., and International Medical Systems, Ltd. The complaint alleges false or misleading advertising and labeling, based on the Lanham Act and equivalent state statutes. The Defendants' motions essentially argue that this Court, in deciding the case, would intrude on matters Congress has left exclusively to the discretion of the FDA. The Plaintiff,

1 on the other hand, argues that its complaint does not rest on  
2 matters requiring the expertise and authority of the FDA to  
3 resolve, and dismissal is not appropriate.

4 For reasons discussed below, the Court grants the motions in  
5 part and denies them in part.

## 6 **I. BACKGROUND**

### 7 *A. Factual Background*<sup>1</sup>

8 Par Sterile Products, LLC ("Par") is a manufacturer of  
9 injectable epinephrine under the brand name ADRENALIN. Defendants  
10 American Regent, Inc. ("American Regent"), Hospira, Inc.  
11 ("Hospira"), and International Medical Systems, Ltd. ("IMS")  
12 (collectively, "Defendants") are manufacturers of other injectable  
13 epinephrine products.

14 In 2012, Par (then known as JHP Pharmaceuticals, LLC)  
15 submitted a New Drug Application ("NDA") for its 1 mL and 30 mL  
16 injectable epinephrine products to the U.S. Food and Drug  
17 Administration ("FDA") under the brand name ADRENALIN. (Compl. ¶¶  
18 3-4.) On December 7, 2012, the FDA, pursuant to its power under  
19 the Food, Drug, and Cosmetic Act ("FDCA"), granted JHP approval to  
20 market and sell the 1 mL version of ADRENALIN. (*Id.* ¶¶ 5-6.)<sup>2</sup> Par  
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22 <sup>1</sup>Both Par and Defendants Hospira and IMS have submitted to the  
23 Court additional material in support of their positions.  
24 "Generally, a district court may not consider any material beyond  
25 the pleadings in ruling on a Rule 12(b)(6) motion." Hal Roach  
26 Studios, Inc. v. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555  
27 n.19 (9th Cir. 1989). Therefore, the Court declines to consider,  
in ruling on these motions, either the Declaration of Harold  
Storey, submitted by Par, or the Declaration of Jeffrey LeVee,  
submitted by Hospira and IMS. This section draws exclusively from  
the complaint for the facts alleged.

28 <sup>2</sup>The NDA for the 30 mL ADRENALIN product was still pending at  
the time JHP filed its complaint. (Compl. ¶ 4.)

1 alleges that it invested millions of dollars in complying with the  
2 FDA approval process. (Id. ¶¶ 50-51.)

3 Par alleges that the Defendants all sell injectable  
4 epinephrine products which are not FDA-approved (Compl. ¶¶ 55, 57),  
5 an allegation which no Defendant denies. Par also alleges that the  
6 Defendants mislead the public in four different ways.

7 First, Par alleges that the Defendants represent to consumers,  
8 either overtly or through misdirection, that their products are  
9 FDA-approved, when they are not. (Compl. ¶ 71.)

10 Second, Par alleges that the Defendants misleadingly advertise  
11 their products as "safe" and "effective."<sup>3</sup>

12 Third, Par alleges that the Defendants advertise products that  
13 are "illegal" to sell or market under the FDCA (Id. ¶¶ 56-57),  
14 while representing to wholesalers and the public that they abide by  
15 the law. Par thus alleges that the Defendants are misleading  
16 wholesalers and the public as to the legality of their products.

17 Fourth, Par alleges that the Defendants omit from their  
18 product labeling certain injection location and adverse reaction  
19 information that Par's product *must* carry as part of its FDA-  
20 approved labeling. This, Par contends, misleads the public into  
21 thinking that Par's product is *more* dangerous than the generics,  
22 because it can only be administered in certain locations and can  
23 cause certain adverse reactions.

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<sup>3</sup>Throughout the complaint, Par's constant refrain is that the  
27 Defendants market their products as "safe, effective, and  
28 FDA-approved." (Compl. ¶ 71.) However, for reasons that will be  
explained below, the Court finds it appropriate to separate the  
safety/effectiveness issues from the question of FDA approval.

1 Par asserts a claim against the Defendants for each of these  
2 representations under the Lanham Act, 15 U.S.C. § 1125(a)(1), which  
3 forbids false or misleading advertising.<sup>4</sup> Par also alleges actual  
4 injury, in the form of both competitive disadvantage and harm to  
5 reputation and goodwill.

6 Defendants counter that Par's Lanham Act claims should be  
7 dismissed, either because they are precluded altogether by the  
8 FDCA, because Par has failed to exhaust its administrative  
9 remedies, or because the FDA has primary jurisdiction over the  
10 claims and the case should be referred to the agency for a ruling.  
11 (Def. American Regent's Mot. Dismiss, § II; Defs. Hospira and IMS's  
12 Reply, § I; Def. American Regent's Reply, "Argument.") Defendants  
13 Hospira and IMS also raise the issue of the factual sufficiency of  
14 Par's claims. (Defs. Hospira and IMS's Mot. Dismiss, § I.C.2.)

15 *B. Procedural Background*

16 The initial complaint in this matter was filed on October 8,  
17 2013, and the Defendants filed motions to dismiss on November 27,  
18 2013. On February 3, 2014, Judge Michael Fitzgerald held a hearing  
19 on the motions. Ultimately, however, the Court ordered the motions  
20 denied without prejudice and the case stayed, pending the  
21 resolution of another Lanham Act/FDCA case in the Supreme Court,  
22 POM Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228 (2014).

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24 <sup>4</sup>Par also alleges violations of the California Business and  
25 Professions Code, §§ 17200 and 17500, which similarly prohibit  
26 misleading advertising. These state law claims, however, are not  
27 substantively addressed in the motions currently under  
28 consideration, however, as all Defendants agree that the state  
claims are "substantially congruent" to the Lanham Act claims.  
(Def. American Regent's Mot. Dismiss, § III.A.; Defs. Hospira and  
IMS's Mot. Dismiss, § II.) Par similarly focuses its arguments in  
opposition on the Lanham Act claims.

1        POM Wonderful was decided June 12, 2014. On June 19, 2014,  
2 the Plaintiff in this case filed notice of the decision, and on  
3 July 23, 2014, the Defendants filed new motions to dismiss, which  
4 are the subject of this order.

## 5    **II. LEGAL STANDARD**

6        A complaint may be dismissed under Rule 12(b)(6) only if it  
7 "either (1) lacks a cognizable legal theory or (2) fails to allege  
8 sufficient facts to support a cognizable legal theory." Somers v.  
9 Apple, Inc., 729 F.3d 953, 959 (9th Cir. 2013). "All allegations  
10 of material fact in the complaint are taken as true and construed  
11 in the light most favorable to the plaintiff." Williams v. Gerber  
12 Products Co., 552 F.3d 934, 937 (9th Cir. 2008). "When there are  
13 well-pleaded factual allegations, a court should assume their  
14 veracity and then determine whether they plausibly give rise to an  
15 entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679  
16 (2009).

## 17    **III. DISCUSSION**

### 18    *A. Failure to Exhaust Administrative Remedies*

19        American Regent, alone among the Defendants, raises the issue  
20 of failure to exhaust administrative remedies. It notes that under  
21 21 C.F.R. § 10.45(b), citizens are required to submit a Citizen's  
22 Petition to the FDA "before any legal action is filed in a court  
23 complaining of the [agency's] action or failure to act." Were  
24 Par's claim that the FDA had acted unlawfully, or that the FDA had  
25 failed to act where it was required to do so, exhaustion would come  
26 into play. Par makes no such claim, nor indeed any claim against  
27 the FDA. Exhaustion of administrative remedies is not required, or  
28 even possible, here.

1 *B. The Lanham Act, the FDCA, and the Scope of the POM Wonderful*  
2 *Holding*

3 Because this action was stayed pending the outcome of the POM  
4 Wonderful case in the Supreme Court, this Court begins its analysis  
5 with the question of how, if at all, that decision has changed the  
6 law of preclusion with regard to Lanham Act cases and the FDCA.

7 The Lanham Act broadly regulates representations made in the  
8 course of commerce. It creates a cause of action against any  
9 person who "uses in commerce any . . . false or misleading  
10 description of fact, or false or misleading representation of fact,  
11 which . . . misrepresents the nature, characteristics [or]  
12 qualities . . . of his or her or another person's goods, services,  
13 or commercial activities." 15 U.S.C. § 1125(a)(1). The purpose of  
14 the Act is "to protect persons engaged in such commerce against  
15 unfair competition" and "to prevent fraud and deception." 15 U.S.C.  
16 § 1127.

17 The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-  
18 399f, on the other hand, is intended "primarily to protect the  
19 health and safety of the public at large." POM Wonderful, 134 S.  
20 Ct. at 2234. Although the FDCA, too, regulates the labeling and  
21 advertising of drugs, see 21 U.S.C. § 352, enforcement is not  
22 through a private cause of action, but almost exclusively through  
23 the actions of the FDA. Apart from a few situations in which  
24 states may initiate enforcement actions, "all such proceedings for  
25 the enforcement, or to restrain violations, of this chapter shall  
26 be by and in the name of the United States." 21 U.S.C. § 337.

27 The Lanham Act and the FDCA are thus two discrete statutory  
28 schemes that can regulate the advertising, marketing, and labeling

1 of food and drugs. Neither, however, precludes the other. In POM  
2 Wonderful, the Supreme Court held that "the FDCA and the Lanham Act  
3 complement each other" and that "Congress did not intend the FDCA  
4 to preclude Lanham Act suits . . . ." 134 S. Ct. at 2241. The  
5 Court noted that while "[e]nforcement of the FDCA and the detailed  
6 prescriptions of its implementing regulations is largely committed  
7 to the FDA," that agency "does not have the same perspective or  
8 expertise in assessing market dynamics that day-to-day competitors  
9 possess." Id. at 2238. Thus, the two statutes serve different  
10 functions and draw on different areas of expertise.

11 On the other hand, while articulating a broad vision of the  
12 statutes as compatible and complementary, the Court did, in  
13 passing, preserve the possibility that *some* Lanham Act suits might  
14 be precluded by the FDCA:

15 *Unlike other types of labels regulated by the FDA, such as*  
16 *drug labels, it would appear the FDA does not preapprove food*  
17 *and beverage labels under its regulations and instead relies*  
18 *on enforcement actions, warning letters, and other measures.*  
19 Id. at 2239 (citation omitted) (emphases added).

20 This passage suggests that, at a minimum, the Court might find  
21 a Lanham Act claim precluded by the FDCA where it turns on the  
22 content of a drug label, especially if that drug label were pre-  
23 approved by the FDA.

24 The Court further suggested, referencing Geier v. American  
25 Honda Motor Co., 529 U.S. 861 (2000), that a Lanham action might be  
26 barred where "the agency enacted a regulation deliberately allowing  
27 manufacturers to choose between different options," or where the  
28 Plaintiff's grounds for the Lanham Act claim otherwise conflict

1 with an affirmative policy judgment by the FDA. POM Wonderful, 134  
2 S. Ct. at 2241.

3 There also exists a considerable body of circuit law, pre-POM  
4 Wonderful, counseling restraint by courts in approaching Lanham  
5 suits with regard to food and drug labeling and advertising. For  
6 example, the Ninth Circuit held, in PhotoMedex, Inc. v. Irwin, 601  
7 F.3d 919 (9th Cir. 2010), that "a private action brought under the  
8 Lanham Act may not be pursued when, as here, the claim would  
9 require litigation of the alleged underlying FDCA violation in a  
10 circumstance where the FDA has not itself concluded that there was  
11 such a violation."

12 PhotoMedex was the primary case relied on by the lower courts  
13 in POM Wonderful, and although it was not specifically overruled,  
14 its precedential value may be limited. But even PhotoMedex  
15 recognized that the FDCA did not fully bar Lanham Act claims, where  
16 the law was clear and did not require the FDA's expertise or  
17 rulemaking authority to determine:

18 If, for example, it was clear that an affirmative statement of  
19 approval by the FDA was required before a given product could  
20 be marketed and that no such FDA approval had been granted, a  
21 *Lanham Act claim could be pursued for injuries suffered by a*  
22 *competitor as a result of a false assertion that approval had*  
23 *been granted.*

24 PhotoMedex, 601 F.3d at 924-25 (emphasis added). And other  
25 circuits have similarly concluded that where the issue of FDA  
26 approval is straightforward, a Lanham action is viable. See  
27 Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir.  
28 2005) (surveying the precedent of multiple circuits and concluding



1 that Lanham Act claims "concerning representations of FDA approval"  
2 are viable *unless* they would require a "preemptive determination"  
3 of an issue within the FDA's exclusive authority).

4 Thus, although the extent of the shift in doctrine after POM  
5 Wonderful is not entirely clear, both the Supreme Court in that  
6 case and the Circuits in prior case law make clear two things.  
7 First, Lanham Act claims (even with regard to FDA approval) are  
8 not, as a general matter, precluded or barred by the FDCA. But  
9 second, *some* claims *may* require the expertise of the FDA to  
10 resolve.

11 Given the strong holding in favor of Lanham claims in POM  
12 Wonderful, all Defendants understandably seek to limit the reach of  
13 that decision, arguing that the case and its holding were about  
14 food labels *only* and did not reach the labeling, marketing, or  
15 advertising of drugs. The broad language of the opinion, however,  
16 does not support that view.

17 It is true that the Court makes frequent mention of "food and  
18 drink" or "food and beverage" in the course of its opinion, *e.g.*,  
19 POM Wonderful, 134 S. Ct. at 2334 ("The FDCA prohibits the  
20 misbranding of food and drink."); *id.* at 2237 ("[F]ood and beverage  
21 labels regulated by the FDCA are not, under the terms of either  
22 statute, off limits to Lanham Act claims."); *id.* at 2238 ("Although  
23 both statutes touch on food and beverage labeling . . . ."); etc.  
24 And, as noted above, the Court suggests a difference between food  
25 labeling, which is not subject to FDA pre-approval, and drug  
26 labeling, which is. *Id.* at 2239.

27 But the arguments, logic, and holding of *POM Wonderful* are  
28 couched in much broader language and strongly suggest a more wide-

1 ranging application. For example, the Court's argument that the  
2 Lanham Act draws on the market expertise of competitors, id. at  
3 2238, does not depend on anything peculiar to food and beverage  
4 labeling. Nor does its argument that "neither the Lanham Act nor  
5 the FDCA, in express terms, forbids or limits Lanham Act claims  
6 challenging labels that are regulated by the FDCA," id. at 2237;  
7 nor does its point that "the Lanham Act and the FDCA have coexisted  
8 since the passage of the Lanham Act in 1946" and Congress has never  
9 sought to address preclusion by one or the other. Id.

10 The logical building blocks of the Court's specific holding  
11 with regard to food and beverage labeling would seem to be equally  
12 applicable to food and beverage advertising, drug marketing,  
13 medical device labeling, cosmetics branding, or any other kind of  
14 marking or representation which would fall under both the Lanham  
15 Act and the FDCA, *unless* preclusion is required for some specific  
16 reason.<sup>5</sup> The general presumption following POM Wonderful, then, is  
17 that Lanham Act claims with regard to FDCA-regulated products are  
18 permissible and, indeed, desirable. Id. at 2231 ("Allowing Lanham  
19 Act suits takes advantage of synergies among multiple methods of  
20 regulation.").

21 *C. Par's Lanham Act Claims*

22 Having established POM Wonderful's general presumption in  
23 favor of Lanham Act claims and against preclusion, the Court now  
24 turns to each of Par's bases for its claims.

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26 <sup>5</sup>As noted above, the Supreme Court suggested two such reasons  
27 in POM Wonderful: the FDA may have pre-approved a particular  
28 labeling scheme, as in the labeling of FDA-approved drugs; or the  
agency may have authorized a menu of possible lawful choices for  
manufacturers, as was the case in Geier. (The common element, of  
course, is positive regulatory action in the matter by the FDA.)

1 1. FDA Approval

2 Par's fundamental argument with regard to FDA approval is that  
3 it is a sort of "Good Housekeeping Seal" for pharmaceuticals: it is  
4 the government's imprimatur on a product, indicating quality,  
5 safety, and desirability. Although some drugs may be lawfully sold  
6 without FDA approval, Part III.C.3 *infra*, if a product *has* been  
7 approved, consumers may take some assurance that it has been  
8 properly tested and meets the agency's minimum quality standards.  
9 This makes an FDA-approved product a more attractive product,  
10 whether at the wholesale, retail, or end user level. But it can  
11 also be expensive to get approval for a drug, so a company that  
12 chooses to invest in getting approval may operate at a competitive  
13 disadvantage if other companies can falsely represent to the public  
14 that their unapproved products are FDA-approved. Thus,  
15 representations that a drug is approved when it is not undermine  
16 the Lanham Act's public policy goals both by confusing consumers  
17 and by enabling unfair competition by producers who have not  
18 bothered to get FDA approval.

19 Par alleges that Defendants have misrepresented their products  
20 as being FDA-approved in several ways. First, Par alleges that  
21 Hospira advertises its product "as an NDA product . . . when, in  
22 fact, Hospira has not obtained FDA approval of such an NDA."  
23 (Compl. ¶ 70.) Second, Par alleges that Hospira, at least,  
24 advertises that Par's ADRENALIN is the "brand name equivalent" of  
25 its own product, and that it is a "generic" version of Par's  
26 product.<sup>6</sup> In a more general way Par alleges that Defendants

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27  
28 <sup>6</sup>Par introduced these specific allegations against Hospira  
(continued...)

1 encourage purchasers to think of their products as "comparable to  
2 or interchangeable with" Par's product. (Id. at ¶ 101.) Par  
3 contends that consumers will believe that Defendants' unapproved  
4 products are interchangeable with Par's approved one. Finally, Par  
5 alleges that Defendants advertise via certain industry lists, and  
6 that consumers expect the products on such lists to be "branded  
7 drugs or generic products," although Defendants' products are not  
8 "generics" as defined by the FDA. (Id. at ¶ 70.)

9 Defendants argue that claims based on such factual allegations  
10 are precluded, even post-POM Wonderful. Defendant American Regent  
11 cites to a recent case in the District of Utah, where the court  
12 found precluded a company's Lanham claim that a competitor was  
13 "falsely advertising that the current [medical device] model has  
14 FDA approval." Catheter Connections, Inc. v. Ivera Med. Corp., No.  
15 2:14-CV-70-TC, 2014 WL 3536573, \*1, \*6 (D. Utah July 17, 2014).  
16 But that case dealt with re-approval of new models of *existing*  
17 medical devices, a circumstance under which the FDA leaves it to  
18 the manufacturer, in the first instance, to determine whether it  
19 must apply for approval again or assume that the approval carries  
20 over. Id. at \*5. Thus, the manufacturer there could plausibly  
21 claim that its product was, in fact, approved, at least until the  
22 FDA determined otherwise—a determination that would, of course, be  
23 entirely within the agency's purview. That is obviously very

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25 <sup>6</sup>(...continued)  
26 only at oral argument. Ordinarily, the Court would be reluctant to  
27 consider such late allegations as part of the complaint. However,  
28 because they sharpened the debate during oral argument, were  
adequately argued by Defendants, and were consistent with the  
other, more general allegations in the Complaint, the Court  
includes them in this discussion.

1 different from the present case, where the Defendants have never  
2 had (and do not claim to have had) their products approved in the  
3 first place.

4 In short, Par's claim is not precluded.

5 Defendants also argue that Par's claim falls under the  
6 "primary jurisdiction" of the FDA. Under the primary jurisdiction  
7 doctrine, a court, though having jurisdiction to hear the  
8 complaint, may in some situations be required to "refer" the matter  
9 to an administrative agency for resolution of a particular  
10 technical issue. See Reiter v. Cooper, 507 U.S. 258, 268 (1993)  
11 ("[C]laims properly cognizable in court [may] contain some issue  
12 within the special competence of an administrative agency."). The  
13 doctrine applies where there is "(1) the need to resolve an issue  
14 that (2) has been placed by Congress within the jurisdiction of an  
15 administrative body having regulatory authority (3) pursuant to a  
16 statute that subjects an industry or activity to a comprehensive  
17 regulatory scheme that (4) requires expertise or uniformity in  
18 administration." United States v. Gen. Dynamics Corp., 828 F.2d  
19 1356, 1362 (9th Cir. 1987).

20 There is no need to invoke primary jurisdiction doctrine as to  
21 this claim. In this instance, it takes no special expertise to  
22 determine whether the FDA has granted approval or not; nor are  
23 there "uniformity of administration" concerns in the court making  
24 that simple factual determination. The FDA itself maintains a  
25 comprehensive list of approved drugs, see FDA, "Drugs@FDA,"  
26 FDA.gov,  
27 <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>  
28 (last visited Aug. 28, 2014), and while there may be cases where

1 approval is a gray area, no Defendant has argued that this is one.  
2 Indeed, the fact that the Defendants' drugs are unapproved is not  
3 contested by any party.

4 The same thing is true of the term "generic." To be declared  
5 a "generic" drug by the FDA, a product must go through an approval  
6 process prescribed by the agency. See "Generic Drugs: Questions  
7 and Answers," FDA.gov (Sept. 3, 2013),  
8 [http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm)  
9 [/ucm100100.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm). But the FDA maintains lists of approved generics,  
10 just as it does for brand-name products. Id. If all that Par  
11 alleges is that Defendants are advertising their products as  
12 approved generics when they are not in fact approved, the Court  
13 need not refer the question to the FDA's expertise to make factual  
14 determinations.

15 Primary jurisdiction is not a bar to Plaintiff's claims here.

16 Defendants also allege that Par's complaint is factually  
17 insufficient to support its Lanham claim. Defendants argue that  
18 Par has not alleged specific statements by the Defendants  
19 representing that their products are FDA-approved. Defendants then  
20 cite primarily to Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th  
21 Cir. 1993) for the proposition that a plaintiff cannot show that  
22 the defendant implied FDA approval solely by introducing evidence  
23 that the defendant put the product on the market.

24 With regard to Defendant Hospira, Par has, in fact, alleged a  
25 specific representation: Par alleges that Hospira advertises its  
26 product as "an NDA product." (Compl. ¶ 70.) While that is not  
27 precisely the same as saying that the product is "FDA-approved," it  
28 could easily be construed that way by the public, who should not

1 bear the burden of uncovering information that contradicts the  
2 impression given by misleading advertising. See, e.g., Williams v.  
3 Gerber Products Co., 552 F.3d 934, 939-40 (9th Cir. 2008) (holding  
4 that the misleading labeling of a largely juice-free candy as  
5 "fruit juice snacks" was not saved from a false advertising claim  
6 by an FDA-approved ingredient list on the side of the box).

7 Therefore Par has made a plausible allegation that Hospira has made  
8 misleading statements about its products' FDA approval status.

9 With regard to the other two defendants, however, it is not so  
10 clear. Mylan, though not binding on this Court, makes a compelling  
11 point: merely putting the product on the market is probably not a  
12 representation that the product is FDA-approved. At the other end  
13 of the factual spectrum, the Ninth Circuit has said that an actual  
14 "false assertion" that the product was approved could sustain a  
15 Lanham Act claim where "it was clear that . . . no such FDA  
16 approval had been granted." PhotoMedex, 601 F.3d at 924-25.

17 Par's complaint falls somewhere between those two clear poles.  
18 With regard to American Regent and IMS, at least, Par alleges no  
19 overt "false assertion." On the other hand, Par's argument is more  
20 subtle than that of the plaintiff in Mylan. Par does not merely  
21 allege that putting the product on the market creates a misleading  
22 impression that the drug is FDA-approved. Rather, it alleges that  
23 the Defendants put their products on industry "Price Lists," and  
24 that "buyers believe that all prescribed drugs identified on the  
25 Price Lists are . . . FDA-approved." (Compl. ¶ 71.) And it  
26 alleges that by listing their drugs as "generics," they are  
27 implying that their products are "equivalents" of Par's FDA-

28

1 approved product, which might mislead consumers into thinking that  
2 Defendants' products are also FDA-approved. (Id. at 70.)

3 The problem, for Par, is that when the alleged representation  
4 is not an overt false statement, but merely misleading in context,  
5 the evidentiary showing required to sustain a Lanham claim is  
6 higher. In such a case, "proof that the advertising actually  
7 conveyed the implied message and thereby deceived a significant  
8 portion of the recipients becomes critical." William H. Morris Co.  
9 v. Grp. W, Inc., 66 F.3d 255, 258 (9th Cir. 1995). Thus, to  
10 succeed on its claims against American Regent and IMS, Par must  
11 allege facts tending to show that the message "our product is FDA-  
12 approved" was actually conveyed to consumers by American Regent and  
13 IMS.

14 Here, Par does allege that consumers suffer actual confusion:  
15 "[B]uyers believe that all prescribed drugs identified on the price  
16 lists are . . . FDA-approved." (Compl. ¶ 71.) While Par has not  
17 yet produced actual evidence of these consumer beliefs, at the  
18 motion to dismiss stage, the Court can accept allegations of such  
19 facts as sufficient.

20 Par's Lanham Act claims that its competitors are falsely  
21 representing their products as having been FDA-approved are neither  
22 precluded by the FDCA nor within the primary jurisdiction of the  
23 FDA. Plaintiff's factual pleadings are sufficient to survive a  
24 motion to dismiss. As to the question of whether Defendants  
25 advertise their products as FDA-approved, the motion to dismiss is  
26 denied.

27 2. "Safe" and "Effective"  
28



1 In its complaint, Par frequently alleges that the Defendants  
2 misleadingly represent their products as "safe, effective, and FDA-  
3 approved." (E.g., Compl. ¶ 72.) A determination of whether the  
4 Defendants' products are "safe" or "effective" might well fall  
5 within the primary jurisdiction of the FDA, or even be precluded  
6 entirely. However, the Court need not decide these issues today.  
7 Par alleges no facts to show that Defendants' products are either  
8 unsafe or ineffective. The repeated inclusion of such language may  
9 well be mere rhetorical excess on Par's part. However, to the  
10 extent that any of the Plaintiff's arguments about FDA approval  
11 rest on a determination of either safety or effectiveness, such  
12 arguments suffer a fatal lack of factual sufficiency. Thus, the  
13 sole question with respect to the surviving claim against  
14 Defendants is whether it overtly represents its products as being  
15 "FDA-approved," and not any question of safety or effectiveness.

16 3. Legality of the Defendants' Products

17 Par further alleges that the Defendants are falsely  
18 representing to consumers that their products "comply with all  
19 applicable laws, including the FDCA."<sup>7</sup> (Compl. ¶¶ 60, 87.) And at  
20 least respecting Defendants Hospira and IMS, the complaint alleges  
21 sufficient facts to support a finding of overt statements to this  
22 effect. For example, Hospira is alleged to claim on its website  
23  
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25 <sup>7</sup>In its Opposition, Par seems to suggest that no finding of  
26 illegality is needed: "Par's complaint is not based on a violation  
27 of the FDCA; it is based on Defendants' deceptive advertising of  
28 their products as equivalent to Par's." (Opp'n § I.B.) However,  
because the complaint raises allegations that the Defendants are  
misleading consumers by claiming to comply with the law, the Court,  
to resolve that claim, would have to make a factual finding with  
regard to the alleged FDCA violations.

1 that its complies with "applicable laws and other requirements."  
2 (Compl. ¶ 62.)

3           However, unlike a mere determination that a drug is or is  
4 not FDA-approved, the allegation that the drugs are being sold  
5 *unlawfully* is an issue that would require a more complex finding  
6 from the agency. Of course, if there were a clear and absolute  
7 rule making it patently unlawful to market any drug without going  
8 through the FDA approval process, it might not be necessary for the  
9 FDA to make a specific finding regarding the Defendants' products  
10 for the court to be able to determine that Defendants' products do  
11 not comply with the FDCA. PhotoMedex, 601 F.3d at 924-25.

12           And at first blush, 21 U.S.C. § 355(a) would seem to provide  
13 such a clear rule: "No person shall introduce or deliver for  
14 introduction into interstate commerce any new drug, unless an  
15 approval of an application filed pursuant to subsection (b) or (j)  
16 of this section is effective with respect to such drug." As even  
17 Par admits (Opp'n, "Factual Background"), however, there are some  
18 exceptions to this seemingly clear rule. Specifically, not all  
19 drugs marketed are "new," and many older drugs, even when updated,  
20 are exempt from the strictures of § 355(a). See 21 U.S.C. §  
21 321(p) (setting out grandfathered exceptions to the definition of  
22 "new drug"); see also FDA, Compliance Policy Guide Sec. 440.100  
23 Marketed New Drugs Without Approved NDAs and ANDAs, FDA.gov (Sep.  
24 16 2011), available at  
25 <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074382.htm> (discussing grandfather clauses in the  
26 FDCA and a "Prescription Drug Wrap-Up" program that brought many,  
27 but not all, old drugs into the fold of FDA approval).

1 In short, unlike the binary factual determination of whether  
2 Defendants' products are, in fact, FDA-approved, the question of  
3 legality directly implicates the FDA's rulemaking authority. The  
4 determination of whether a drug is "new," and whether it can be  
5 lawfully marketed under the FDCA, involves complex issues of  
6 history, public safety, and administrative priorities that Congress  
7 has delegated exclusively to the FDA.

8 That does not mean, however, that an allegation of illegality  
9 under the FDCA could *never* form the basis of a successful Lanham  
10 Act claim. As PhotoMedex and POM Wonderful both make abundantly  
11 clear, where the court is not called upon to make determinations  
12 within the exclusive purview of FDA authority, a Lanham Act claim  
13 may be heard, even if the subject of the claim touches the area of  
14 authority of the FDCA. Thus, this claim is not precluded as a  
15 categorical matter. If the Plaintiff were to pursue the matter with  
16 the FDA through its administrative procedures and obtain a clear  
17 statement from the agency that the Defendants are selling their  
18 products illegally or otherwise breaking the law, *and* if the  
19 Defendants at that point chose to affirmatively declare in their  
20 advertising that their products comply with the law, a federal  
21 court could hear a Lanham Act claim for false advertising.

22 But this Court cannot proceed on this claim without a clear  
23 statement by the FDA. To do so would be to arrogate the authority  
24 of the FDA to decide, at least in the first instance, the legality  
25 or illegality of marketing a particular substance. "It is clear to  
26 us that FDA has power to determine whether particular drugs require  
27 an approved NDA in order to be sold to the public. FDA is indeed  
28 the administrative agency selected by Congress to administer the

1 Act, and [it] cannot administer the Act intelligently and  
2 rationally unless it has authority to determine what drugs are 'new  
3 drugs' . . . and whether they are [grandfathered]." Weinberger v.  
4 Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 624 (1973).

5 In short, in order to resolve Par's Lanham Act claim based a  
6 factual allegation that the Defendants are falsely claiming to  
7 comply with the law while in fact selling illegal products, the  
8 Court must resolve an issue that Congress has placed "within the  
9 jurisdiction of an administrative body having regulatory  
10 authority," under a comprehensive regulatory scheme. Gen. Dynamics  
11 Corp., 828 F.2d at 1362. And, crucially, this is not a question  
12 that can be resolved without expertise. Id. Moreover, Congress's  
13 decision to centralize authority to determine the legality of drug  
14 sales in the FDA was obviously intended to provide "uniformity of  
15 administration." Id. Thus, it seems clear that Par's Lanham Act  
16 claim with regard to legality requires a determination that is  
17 within the primary jurisdiction of the FDA.

#### 18 4. Misleading Labeling

19 Finally, Par argues that the Defendants mislead the public by  
20 not including, in their packaging and labeling, all of the caveats  
21 and warnings that Par's product must carry under the terms of its  
22 FDA approval. This, it is alleged, creates the impression that  
23 Par's product is *less* safe, because it comes with *more* warnings  
24 than the Defendants' unapproved products.

25 Even if this allegation is true, Par faces several hurdles to  
26 basing a Lanham Act claim on it. First, because the deceit alleged  
27 is by implication rather than an overt false statement (such as  
28 "Par's ADRENALIN is less safe than our product!"), Par has the

1 burden of pleading at least some facts tending to show that the  
2 alleged implied message is actually transmitted to the consumer.  
3 William H. Morris, 66 F.3d at 258. Here the pleading is thin at  
4 best. Par does not allege facts tending to show that the negative  
5 message about its product is actually conveyed to consumers.  
6 Indeed, the message is at least ambiguous: a savvy consumer of  
7 pharmaceuticals, used to many pages of dire warnings, might well be  
8 put *on guard* by the lack of similar warnings on the Defendants'  
9 products.

10 Even if Par's pleading were sufficient to show that the  
11 alleged implied message is actually transmitted to consumers,  
12 however, the area of drug labeling was specifically singled out by  
13 the POM Wonderful Court as being one where the FDA takes a  
14 particularly active role. POM Wonderful suggested, at least  
15 obliquely, that drug labeling might be an area where Lanham Act  
16 claims are precluded.

17 Par argues that because the Defendants' products are  
18 unapproved, they are effectively unregulated by the FDA. (Opp'n §  
19 I.C.) There is, perhaps, some merit to this argument. Unlike the  
20 situation envisioned in POM Wonderful, where the FDA would have  
21 *pre-approved* a drug label, here Par correctly points out that the  
22 FDA has taken no action at all with regard to these labels. Thus,  
23 this case might not fall within POM Wonderful's caveat-in-dictum.

24 However, the Court need not resolve this thorny issue, because  
25 there is a third, truly fatal problem with Par's allegation:  
26 namely, it requires the Court to determine, as a matter of fact,  
27 that Par's ADRENALIN is *not* less safe than the Defendants' various  
28 products. After all, if ADRENALIN were less safe, the implied

1 message would not be false or misleading; it would be correct. Par  
2 may find it obvious that its product is not less safe than the  
3 Defendants' products, but it has not alleged any particular facts  
4 tending to prove the comparative safety of the various products  
5 involved.<sup>8</sup>

6 Because the Plaintiff's Lanham Act claim based on false or  
7 misleading labeling requires a showing of facts not properly  
8 pleaded, this claim is dismissed as to all Defendants.

#### 9 **IV. CONCLUSION**

10 For all the reasons discussed above, Plaintiff's Lanham Act  
11 claim and corresponding state law claims based on false  
12 representations of FDA approval survive, and the Defendants'  
13 motions are denied.

14 Plaintiff's claims based on false or misleading  
15 representations that the Defendants's products comply with the law  
16 are dismissed without prejudice, so that the Plaintiff can, if it  
17 wishes, file a petition with the FDA to have its competitors'  
18 products declared unlawful.

19 Finally, any claims based on representations that the  
20 Defendants' products are "safe" and/or "effective" are dismissed.  
21 Claims that the Defendants' labels and packaging are misleading  
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27 <sup>8</sup>Even if Par had alleged such facts, however, the safety  
28 determination would almost certainly require the scientific  
expertise of the FDA, and so would likely fall within the agency's  
primary jurisdiction.

1 because they imply that their products are safer than Plaintiff's  
2 are also dismissed.

3 The motions to dismiss are thus granted in part and denied in  
4 part.

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6 IT IS SO ORDERED.

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Dated: October 7, 2014

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DEAN D. PREGERSON  
United States District Judge

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